

Remarks/Arguments:

Introduction

Claims 50-90 are pending. Claims 68-90 are withdrawn. Claim 55 has been amended to recite “the substantially uniform cross-section bore portion (14)”. Now new matter is introduced with this amendment. Entry of the claim amendment is respectfully requested.

Section 112 Rejections

Claim 55 is rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite because of the term “uniform bore portion” in lines 6-7. Applicants respectfully traverse.

Applicants respectfully disagree with the Examiner’s objection in respect of the terms “a substantially uniform cross-section” and “the uniform bore portion” in Claim 55, and respectfully submit that no actual lack of clarity exists. In this connection, the term “the uniform bore portion” has been amended to read “the substantially uniform cross-section bore portion” for consistency. Consistent with the ordinary meaning of the word, the term “uniform” is directed to as having “always the same form” or “not varying or variable”, etc.¹ In the context of the description of the present application (see page 15, lines 5 to 9 of the application as filed on entry into the U.S. National Phase), with reference to Figure 1, it is clear that the term “substantially uniform cross-section” of the bore portion (14) is used in order to distinguish the shape of the cross-section of the bore portion (14) from the cross-section of the adjacent bore portion (13) which converges towards the open end (2) of the valve (1). Specifically, as shown

¹ uniform *a.* 1. Of one unchanging form, character, or kind; that is our stays the same in different places or circumstances, or at different times. (THE NEW SHORTER OXFORD ENGLISH DICTIONARY 3488 (Thumb Index ed. 1993).

uniform *adj.* 1a) always the same; not varying or changing in form, rate degree, manner, etc.; constant; 2a) having the same form, appearance, manner, etc. (WEBSTER’S NEW WORLD DICTIONARY 1458 (3rd col. ed. 1994).

uniform *adj.* 4. Unvaried in texture, color, or design. (THE AMERICAN HERITAGE COLLEGE DICTIONARY 1474 (3rd ed. 1993).

in Figure 1, in contrast with the second bore portion 13, the walls of the first bore portion (14) are parallel to the central (longitudinal) axis of the entire bore 4. It follows that the transverse dimension (e.g. diameter or width, in case the bore is not circular in plane) of the first bore portion (14) does not vary along its longitudinal axis. In other words, the transverse dimension of first bore portion (14) remains the same at any given point along the longitudinal axis, i.e. stays uniform. It is well known that the term “cross-section” in relation to a bore is almost exclusively used in industry to refer to size or shape of the bore in the direction of its longitudinal axis, as in the present case. For the above reasons, Applicants respectfully submit that the term “substantially uniform cross-section” of the first bore portion (14) is clear.

Reconsideration and withdrawal of the Section 112 rejection is respectfully requested.

Section 102 Rejections

Claims 50-58 and 62-63 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by US 6,491,283 to Newberg (hereinafter “Newberg”). Applicants respectfully traverse.

With regard to the Claim Rejections of Claims 50-58 and 62-63 Newberg does not anticipate the valve of the present invention.

Specifically, the feature of present Claim 50:

“wherein one of the plastic portions has a protruding sharp rim (15) and the other plastics portion of the seal has a curved surface area (22) so that when the valve (1, 121, 700, 800, 400, 900, 990) is in the closed position, the sharp rim (15) engages the curved surface area (22) and displaces a portion of the curved surface area (22) thereby elastically deforming the materials of the sharp rim (15) and the curved surface area (22) to seal the opening of the valve (1, 121, 700, 800, 400, 900, 990)” (emphasis added)

is not disclosed in the Newberg reference.

At col. 5, lines 60-67 of Newberg, with reference to all the embodiments of the valve of Newberg, it is stated that:

"It should be noted that all of the internal passages of the valve which are in contact with the process material should be rounded in order to avoid any sharp corners where the process material, cleaning materials, steam, etc. may accumulate. Several of the Figures in the present application illustrate sharp corners, although it is preferable that curved corners be included". (emphasis added)

Thus, first of all, Newberg clearly teaches away from the idea of providing a sharp rim on a portion of the valve and quite on the contrary requires that all the sharp corners of the valve be rounded in order to avoid accumulation thereon of the process material. Hence there is no sharp rim described in Newberg that can penetrate the curved surface area to form a seal.

Furthermore, Newberg provides no mention whatsoever that the two portions of the seal engage each other and deform so that a portion of the curved surface area is displaced upon engagement and the two portions become elastically deformed, as required by present Claim 50 in order to bring the two portions into a positive snug contact and form a reliable seal that can withstand the rigors of a sterilization process and maintain its integrity. Rather, in all Figures of Newberg, including Figure 9 relied upon by the Examiner, surface contact between the sealing cap 83, 74 and the annular flat sealing surface 21 is illustrated. Since all the corners of Newberg are rounded and there is no sharp rim to engage the curved surface area, no displacement of a portion of the curved surface area and no elastic deformation occur as a result. Specifically referring to Figure 9 of Newberg, it is clear from the drawing that the curved sealing surface 84 remains un-deformed upon contact with the flat sealing surface 21.

In addition, there is no disclosure provided in Newberg of the material of the seal portions being plastics material.

For the above reasons, it is respectfully submitted that Claim 50 is novel having regard to Newberg.

Therefore, reconsideration and withdrawal of the rejection of claims 50-58 and 62-63 are rejected under 35 U.S.C. §102(b) to Newberg is respectfully requested.

Section 103 Rejections

A.) Claims 61 and 64-66 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Newberg in view of US 6,237,639 to Jouglu et al (hereinafter "Jouglu"). Applicants respectfully traverse.

As described above, Newberg fails to disclose, teach or suggest the subject matter of independent claim 50. Jouglu is cited by the examiner for certain alleged teachings regarding means for displaying to a user the actuation state of a valve, etc.

Jouglu, however, fails to cure the deficiencies of Newberg. Accordingly, claims 61 and 64-66 are patentably distinct over Newberg and Jouglu.

Reconsideration and withdrawal of the rejection of claims 61 and 64-66 are patentably distinct over Newberg and Jouglu.

B.) Claims 50 and 59-65 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over WO 03/090842 to Liepold et al (hereinafter "Liepold") in view of US 7,270,673 to Trumbower et al. (hereinafter "Trumbower"). Applicants respectfully traverse.

Validity of Trumbower as a prior art reference

It is respectfully submitted that the subject-matter of Figures 12 to 19a of Trumbower and related description at col. 10, line 31 to col. 12, line 59 are not disclosed in the U.S. provisional application No. 60/482,342 dated June 25, 2003 which is claimed as a priority date in the Trumbower reference. For this reason, the above subject-matter should only be entitled to the

actual date of filing of Trumbower, i.e. June 24, 2004. The priority date of August 1, 2003 of the present application precedes this effective date of Trumbower and the subject matter of Claim 50 is properly entitled to this priority date.

Therefore, the subject-matter of Trumbower relied upon in the Office Action, namely, Figures 16a, 18, 18a and 19a and related description is not valid prior art for the present application.

Accordingly, claims 50 and 59-65 are patentably distinct over Liepold and Trumbower because, *inter alia*, Trumbower, as applied by the examiner, is not valid prior art for a *prima facie* case of obviousness. Therefore, reconsideration and withdrawal of the rejections of Claims 50 and 59-65 under 35 U.S.C. §103(a) are respectfully requested.

Obviousness, Liepold in view of Trumbower

Nevertheless, for the sake of good order, with regard to the claim rejections of claims 50 and 59-65 at paragraph 6, page 10 of the Office Action, Applicants have considered the prior art reference Liepold in view of Trumbower. For the reasons set forth below, the valve of the present invention as defined in present Claim 50 is patentably distinct over Liepold in view of Trumbower.

Specifically, the feature of present Claim 50:

“wherein one of the plastic portions has a protruding sharp rim (15) and the other plastics portion of the seal has a curved surface area (22) so that when the valve (1, 121, 700, 800, 400, 900, 990) is in the closed position, the sharp rim (15) engages the curved surface area (22) and displaces a portion of the curved surface area (22) thereby elastically deforming the materials of the sharp rim (15) and the curved surface area (22) to seal the opening of the valve (1, 121, 700, 800, 400, 900, 990)”

is not disclosed, taught or suggested in either Liepold or Trumbower.

The disclosure of Figures 16a, 18, 18a and 19a of Trumbower referred to by the Examiner is completely unrelated to the claimed subject-matter. Firstly, the sharp rim 689 shown in Figure 16a belongs to the braze body 617 (col. 10, line 38) and is therefore not made from plastics material. The other portion of the seal, i.e. nose 642 of stem 619 does not have a curved surface area engageable with the first seal portion. Contrary to the Examiner's opinion surface 642 shown in Figures 18, 18a and 19 is clearly straight and not curved. The other portion of the seal (nose 642 of stem 619) is not made from plastics material. In fact, the material of the stem 619 or stem 19 of other embodiments of Trumbower is not specified at all. No mention whatsoever can be found throughout Trumbower that the sharp rim 642 displaces a portion of the surface 642 thereby elastically deforming the materials of the sharp rim and the surface area 642. At col. 11, lines 57-59 Trumbower states that "when the valve stem nose 642 sealingly abuts braze body sealing shoulder 689, valve stem 19 can no longer move". In no way can this phrase be interpreted that the shoulder 689 displaces a portion of the nose 642.

The overlap between the nose 642 and the shoulder 689 visible in Figure 19a and seemingly relied upon by the Examiner is meaningless without a description and in fact looks more like a defect of the drawing than the intention of the reference, especially considering the figure depicts a cross-sectional view of apparently non-transparent components. The reliance by the Examiner on this portion of Figure 19 represents a purely *ex post facto* analysis based on hindsight knowledge of the present invention, which is impermissible.

Liepold itself does not provide any teaching or suggestion for modifying the valve of Liepold in order to arrive at the valve as taught by the present invention. The valve of Liepold is a single-use valve. In its original closed state, the seal 2a of the Liepold valve is formed continuously with the body of the valve and once broken the seal cannot be reinstated. Once the seal has been broken upon actuation of the valve, a stop means formed by teeth 2h and notches 5i is specifically provided in the Liepold valve to prevent the valve from being returned into the original position in order to avoid hazard or misuse. Liepold, therefore, teaches away from re-

closing the valve and from forming a seal by bringing the valve from an open into a closed state. Claim 50 therefore cannot be arrived at starting from Liepold alone.

Thus, assuming *arguendo* that Trumbower somehow could be applied, the combination of Liepold and Trumbower fails to arrive at the present invention. Reconsideration and withdrawal of the rejections of Claims 50 and 59-65 under 35 U.S.C. §103(a) are respectfully requested.

C.) Claim 67 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Liepold in view of Trumbower further in view of US 1,387,446 to Astier (hereinafter “Astier”). Applicants respectfully traverse.

Astier is cited by the Examiner for certain alleged teachings regarding seals and seal displacement means. It is respectfully submitted, however, that Astier fails to cure the deficiencies of Liepold and Trumbower. Reconsideration and withdrawal of the rejections of claims 67 under 35 U.S.C. §103(a) is respectfully requested.

Summary

Therefore, Applicants respectfully submit that claims 50-67 are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited, including rejoinder and allowance of the withdrawn claims 68-90.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,

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